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Dockets Management Branch (HFA-305) Docket Number 00N-1269 Food and Drug Administration 5530 Fishers Lane Room 1061 Rockville, MD 20857

February 23, 2001

I am writing in regard to the proposed changes to package inserts for medicines. The FDA should ensure that all reported medicinal adverse reactions—common, less common, and rare—are listed on the new drug labels, as well as the chemical name and inactive ingredients. The complete monograph as found in the Physician's Desk Reference should be reprinted for every drug package insert. Patients also need this information. It should be included with the medicine. Not including it would inconvenience too many people. With the exorbitant amount of money many medicines cost, including the complete monograph is very helpful and fair to patients.

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OON-1269







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